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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARK SIRAVO and GLEN PIERSON

Appeal 2015-004771
Application 12/524,427
Technology Center 3700

Before: JENNIFER D. BAHR, LEE L. STEPINA, and SEAN P. O'HANLON, *Administrative Patent Judges*.

STEPINA, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants[1] appeal under 35 U.S.C. § 134 from the Examiner's decision to reject claims 1, 12–25, 27, 28, and 32–38. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify DePuy Synthes Products, LLC as the real party in interest. Appeal Br. 2.

CLAIMED SUBJECT MATTER

The claims are directed to an implant devices constructed with metallic and polymeric components. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A device for treating bone, comprising:
>
> an intramedullary nail having a rigid body including a metallic core and a polymeric casing extending over at least a target portion of the metallic core to which a locking element extending into the bone is to be permanently bonded by melting a portion of an outer surface of the locking element and the polymeric casing, wherein the casing extends distally beyond a distal end of the metallic core to define a non-metallic distal tip having a tapered wall extending along a first side thereof so that a thickness of the intramedullary nail tapers from a first thickness at the distal end of the metallic core to a second reduced thickness at a distal end of the distal tip of the nail,
>
> wherein the locking element is formed as a locking tack with a shaft and a head having a diameter greater than that of the shaft, and
>
> wherein the distal end of the locking tack includes at least two angled faces extending from a distal tip on the shaft of the locking tack toward the head of the locking tack to increase the outer surface area of the locking tack and form a concave relief at the distal tip and a protruding portion in the concave relief at a junction of the at least two angled faces.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Aeschlimann '666[2]	US 6,913,666 B1	July 5, 2005
Aeschlimann '341[3]	US 2004/0030341 A1	Feb. 12, 2004
Bramlet	US 2004/0193162 Al	Sept. 30, 2004
Rousseau	US 2005/0240189 Al	Oct. 27, 2005
Schlienger	US 2006/0149248 Al	July 6, 2006
Bonutti	US 2007/0270833 A1	Nov. 22, 2007

REJECTIONS[4]

(I) Claims 1, 12, 14–20, 27, 28, and 32 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bonutti, Aeschlimann '341, and Aeschlimann '666.

(II) Claim 13 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bonutti, Aeschlimann '341, Aeschlimann '666, and Rousseau.

(III) Claims 21 and 23–25 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bonutti.

(IV) Claim 22 is rejected under 35 U.S.C. § 103(a) as unpatentable over Bonutti and Schlienger.

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[2] Appellants and the Examiner refer to this reference as "Aeschlimann2." *See, e.g.*, Final Act. 3, Appeal Br. 5.

[3] Appellants and the Examiner refer to this reference as "Aeschlimann1." *See, e.g.*, Final Act. 3, Appeal Br. 5.

[4] The Examiner withdrew rejections of claims 12 and 14 under 35 U.S.C. § 112, second paragraph, as indefinite, and a rejection of claims 11, 29–31, and 39 under 35 U.S.C. § 103(a) as unpatentable over Bonutti, Aeschlimann '341, Aeschlimann '666, and Bramlet. Adv. Act. 1; Ans. 22–23.

(V) Claims 33–38 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bonutti and Aeschlimann '666.

OPINION

Rejection (I), claims 1, 12, 14–20, 27, 28, and 32

The Examiner finds that Figures 23C–23D of Bonutti disclose many of the features recited in claim 1, but do not disclose a first locking element with at least two angled faces as recited, and the Examiner relies on the embodiment depicted in Figure 12E of Bonutti to remedy this deficiency. Final Act. 3–4. The Examiner also finds that Bonutti is silent regarding a casing extending distally beyond a distal end of a metallic core of the nail and defining a non-metallic distal tip having a tapered wall. Final Act. 5. Nonetheless, the Examiner finds that Aeschlimann '341 teaches a

> casing (57) extend[ing] over the core (63) to define a non-metallic distal tip (tip made from only the thermoplastic casing) having [a] tapered wall extending along a first side thereof so that a thickness of the intramedullary nail tapers from a first thickness at the distal end of the metallic core to a second reduced thickness at a distal end of the distal tip.

Final Act. 5. The Examiner provides an annotated copy of Figure 28 of Aeschlimann '341 indicating where the Examiner finds the non-metallic tip (Final Act. 6), which we reproduce below.

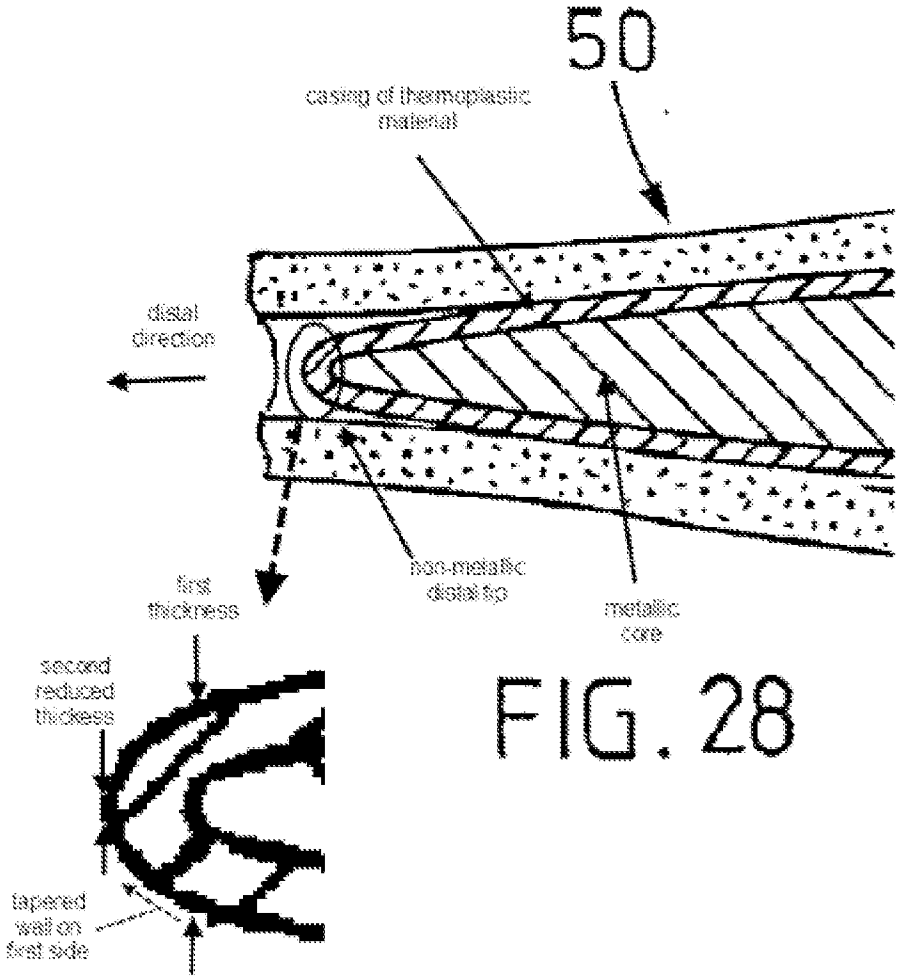

FIG. 28

The Examiner's annotated copy of Figure 28 of Aeschlimann '341 depicts tubular bone 50 in which stem 63 of implant 7 is located. Final Act. 5; Aeschlimann '341 ¶¶ 97–98. The annotated copy of Figure 28 also includes a detail view of the distal tip of the implant 7 indicating where the Examiner finds an area of reduced thickness. The Examiner reasons that it would have been obvious to modify Bonutti to include a tapered tip as disclosed by Aeschlimann '341 to provide easier insertion. Final Act. 7.

Appellants argue that Aeschlimann '341 does not disclose that its casing extends distally beyond the end of the stem. Appeal Br. 6. In this regard, Appellants assert that Figure 28 of Aeschlimann '341 shows the state of the casing only after it has been melted, and Figure 28 does not indicate

the shape of the casing before it is melted. Appeal Br. 6. Appellants assert that the text of Aeschlimann '341 does not support the Examiner's finding that the casing is tapered. Appeal Br. 6–7. Appellants also argue that "Aeschlimann['341] never once states that the casing is uniform around the stem 63, only that there is a 'positive fit connection' to the stem," the casing in Aeschlimann '341 appears thicker at its proximal end than at its distal end, and "no conclusion about uniformity can be drawn from [Figure 28] alone." Appeal Br. 7.

In response, the Examiner reiterates that Figure 28 of Aeschlimann '341 may be relied upon for the above-noted feature, and the Examiner states, "there are no limitations in the claims towards a melted state vs. a non-melted state of the coating. Figure 28 of Aeschlimann['341] clearly shows the casing following the contours of the tapering metal core resulting in a tapered non-metallic distal tip." Ans. 27.

In reply, Appellants assert Aeschlimann '341 "fails to disclose or suggest that this *coating* tapers from a first thickness to a second thickness as it extends distally beyond the distal end of the titanium stem to define a non-metallic distal tip. Rather, the reference states only that the coating is arranged around the stem." Reply Br. 4 (emphasis added). Appellants further argue, "at no point does Aeschlimann['341] teach or suggest that the *casing* of the intramedullary nail extends distally beyond the distal end of the titanium stem, much less that the casing extending distally beyond a distal end of the titanium stem in a tapered fashion" and "because the casing is subsequently melted once the intramedullary nail is inserted into the bone, the external shape of the casing as it extends beyond the distal tip would

have little importance and thus, no conclusion about distal end of the casing can be drawn." Reply Br. 4–5.

> Additionally, in the Reply Brief, Appellants argue,
>
> there is no support anywhere in the Specification or Drawings of Aeschlimann['341] for the Examiner's argument that a tapered shape of the tip of the casing *would be more beneficial than a flat shaped tip* because once the intramedullary nail is inserted into the tubular bone, the casing is liquefied to press into the pores of the surrounding cancellous bone.

Reply Br. 4 (emphasis added). Appellants also reassert that "one of ordinary skill in the art would not reasonably ascertain from Fig. 28 that the casing is applied in a uniform manner around the stem so that it tapers to a distal tip because Fig. 28 shows a non-uniform casing" and that Aeschlimann '341 does not disclose that its drawings are to scale. Reply Br. 5–6.

We do not agree with Appellants' arguments. We reproduce Figure 28 of Aeschlimann '341 below.

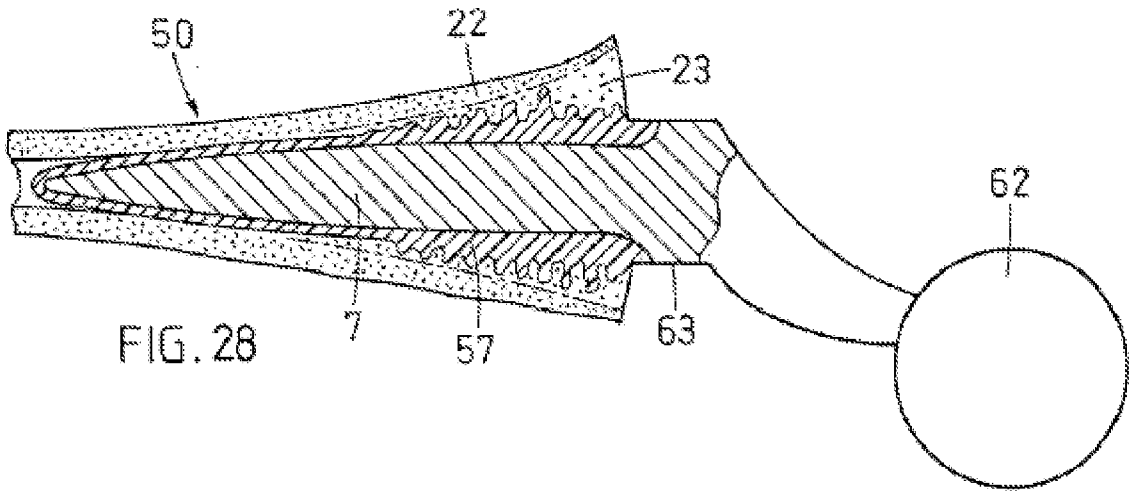

FIG. 28

Figure 28 of Aeschlimann '341 depicts tubular bone 50 in which artificial joint element 62 is attached via stem 63 of implant 7 surrounded by liquefiable material 57. Aeschlimann '341 ¶¶ 97–98.

The end of implant 7 is depicted as covered by material 57, which the Examiner finds corresponds to a casing as recited in claim 1 (Final Act. 5). Although Figure 28 is a cross-section of the arrangement of implant 7, tubular bone 50, and material 57; paragraph 98 of Aeschlimann '341 indicates that stem 63 may be surrounded by liquefiable material, i.e., by material 57. Thus, a person of ordinary skill in the art would understand that material 57 extends around stem 63. *See* Reply Br. 4 ("Aeschlimann['341] discloses an intramedullary implant having a titanium stem with a liquefiable coating around the stem."). Because material 57 extends around stem 63, it also extends beyond stem 63. This is explicitly depicted in Figure 28 where material 57 extends farther to the left in the drawing than stem 63 extends. *See* Final Act. 6, annotated Figure 28.

With respect to Appellants' argument that Figure 28 depicts material 57 only after melting (Appeal Br. 6), whether the arrangement depicted in Figure 28 is before or after melting and solidification, material 57 satisfies the requirement in claim 1 for a

> casing extend[ing] distally beyond a distal end of the metallic core to define a non-metallic distal tip having a tapered wall extending along a first side thereof so that a thickness of the intramedullary nail tapers from a first thickness at the distal end of the metallic core to a second reduced thickness at a distal end of the distal tip of the nail.

In this regard, claim 1 does not limit the shape of the casing such that this shape must be present without there having been any melting.

As for Appellants' allegation that Aeschlimann '341 "fails to disclose or suggest that this coating tapers from a first thickness to a second thickness" (Reply Br. 4), we note that claim 1 requires the thickness of the intramedullary *nail* to taper in this manner, not that the coating/casing do so

independently of the nail. Thus, Appellants' argument on this point is not commensurate with the scope of claim 1.

Similarly, regarding Appellants' contention that Aeschlimann '341 fails to disclose a casing that is uniform and the casing in Aeschlimann '341 "appears thicker at its proximal end than at its distal end" (Appeal Br. 7), claim 1 recites no limitations as to the uniformity of the casing. In other words, the taper required by claim 1 may be present even if the thickness of material 57 is not uniform, and Figure 28 of Aeschlimann '341 depicts the structure at issue, regardless of any alleged variation in thickness of material 57.

As for Appellants' argument that there is no support in Aeschlimann '341 that a tapered tip would be beneficial because it is not disclosed as tapered before melting (Reply Br. 4–5), this assertion is unpersuasive. The Examiner's reasoning is supported by rational underpinnings inasmuch as a tapered tip would allow easier insertion of a device as implemented in the Examiner's proposed combination of Bonutti and Aeschlimann '341. Appellants do not contest that a tapered tip would allow easier insertion. To the extent that Appellants insist upon an explicit motivation in the prior art to establish obviousness, the Supreme Court has stated that a rigid insistence on teaching, suggestion, or motivation is incompatible with its precedent concerning obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). The Court noted that an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for [an examiner] can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418. Instead, the relevant inquiry is whether

the Examiner has set forth "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418. Thus, Appellants' contention that "[Aeschlimann '341] provides no indication that a tapered distal tip of the casing would be beneficial over a flat shaped distal tip" (Reply Br. 5) is unavailing.

We have considered all of Appellants' arguments for the patentability of claim 1, but the Examiner has the better position. Accordingly, we affirm the Examiner's rejection of claim 1 as unpatentable over Bonutti, Aeschlimann '341, and Aeschlimann '666. Appellants rely on the same arguments for the patentability of independent claim 12 (Appeal Br. 8–9), and for the same reasons discussed regarding the rejection of claim 1, we affirm the rejection of claim 12 as unpatentable over Bonutti, Aeschlimann '341, and Aeschlimann '666. Appellants make no additional arguments for claims 14–20, 27, 28, and 32 (Appeal Br. 8–9), all of which depend from either claim 1 or claim 12, and these claims fall with claims 1 and 12.

Rejection (II), claim 13

Appellants do not make additional arguments for the patentability of claim 13 (Appeal Br. 9), and this claim falls with respective independent claim 12.

Rejection (III), claims 21 and 23–25

Claim 21 recites, in part:

> situating a bone plate over a first target portion of a bone, the bone plate formed of a rigid metallic body having a first opening formed therethrough, the first opening housing a

> polymeric portion therethrough, a diameter of the first opening tapering from a first diameter at a non-bone contacting side of the bone plate to a second diameter at a central portion of the bone plate, the first diameter being greater than the second diameter;
>
> inserting a first locking element at any of a plurality of angles through the polymeric portion and into a first locking element receiving bore formed in the first target portion of the bone.

Appeal Br. 20 (Claims App.).

The Examiner relies on Figures 25A–25B of Bonutti to teach many of the features in claim 21, but relies on Figures 27A–27C to teach the recited limitations relating to the first and second diameters of the opening in the rigid metallic body. Final Act. 21–22. The Examiner reasons that it would have been obvious "to modify the opening of the bone plate of the embodiment of Fig. 25A-B with the tapered opening of Fig. 27C in order to accommodate a smooth spherical headed fastener thus providing a surface best conforming to said fastener in order to best bond the two components together." Final Act. 22. Regarding the "inserting" process recited in claim 21, the Examiner finds:

> The first locking element or fastener (432) can be inserted initially (*the tip of the fastener can be inserted*) at any angle (any of a variety of angles as is evidenced in the modified figure below), as the tip of the fastener is smaller in diameter than the first diameter of the opening in the bone plate (the tip of the fastener has a smaller diameter than the head of the fastener), and the shape of the opening in conjunction with the shape of the fastener will align the fastener as it moves through the length of the opening and into the bone.

Final Act. 22 (emphasis added). Further, in the Advisory Action, the Examiner finds that

> a perpendicular angle to the bone (inserting the locking element at 90 degrees relative to the longitudinal axis of the bone and/or plate) satisfies the claim limitation of "inserting a first locking element at any of a plurality of angles" as 90 degrees is an angle within any of a plurality of angles.

Adv. Act. 2.

Appellants assert that only the *tip* of the fastener in Bonutti can be inserted into the opening in the opening of the bone plate in Bonutti, and this fails to satisfy the requirement in claim 21 for inserting a first locking element at any of a plurality of angles. Appeal Br. 12. Appellants also argue that claim 21 requires more than the ability to insert the locking element at only a single angle such as at an angle of 90 degrees. Appeal Br. 12–13.

In response, the Examiner reiterates that claim 21 does not require more than the tip of the locking element to be inserted. Ans. 28. Additionally, the Examiner states:

> the language of "at any of a plurality of angles" is a limitation that reads on a single angle — a single angle selected from a plurality, in other words, Examiner is interpreting this limitation as 'at least one of a plurality of angles'. Appellant's argument that this limitation requires more than just one angle does not correspond with the claim language.

Ans. 29.

In reply, Appellants argue that inserting only the tip of the fastening element into the plate does not position the fastening element into the target portion of a *bone* as recited. Reply Br. 9–10. As for how the fastening element is inserted, Appellants contend, "The first locking element, according to the claim language, must be able to be inserted at any of a

plurality of angles. That is, more than just one angle relative to the longitudinal axis of the bone." Reply Br. 10.

We do not agree with Appellants' interpretation of claim 21 as requiring the ability to insert at more than one angle. Appellants' argument relies on providing a structure capable of receiving a fastening element at any of a plurality of angles, whereas the broadest reasonable interpretation of method claim 21 requires only one insertion action, which is performed at only one angle. In other words, claim 21 does not require multiple insertion steps, each performed at a different angle, and claim 21 does not require providing structure capable of such steps. Rather, claim 21 recites, in pertinent part, "inserting a first locking element at any of a plurality of angles through the polymeric portion and into a first locking element receiving bore formed in the first target portion of the bone." Appeal Br. 20 (Claims App.). Thus, inserting the fastening element, at a *single angle and into the bone* as the Examiner finds is disclosed by Bonutti, satisfies the limitation in claim 21 argued by Appellants. *See* Ans. 29 ("the first locking element of Bonutti being inserted entirely through the plate and entirely into the bone at 90 degrees relative to the longitudinal axis of the bone and/or plate satisfies the claim limitation."). Accordingly, we affirm the Examiner's rejection of claim 21 as unpatentable over Bonutti. Appellants make no additional arguments for claims 23–25 (Appeal Br. 13), and these claims fall with claim 21, from which they depend.

Rejection (IV), claim 22

Appellants make no additional arguments for the patentability of claim 22, which depends from claim 21. Appeal Br. 14–15. Accordingly, claim 22 falls with claim 21.

Rejection (V), claims 33–38

Appellants make the same arguments for the patentability of claim 33 as those discussed above for claim 21. Appeal Br. 14. Accordingly, we affirm the Examiner's rejection of claim 33 for the reasons discussed above. Additionally, we note that claim 33 does not recite any limitation corresponding to the above-noted "inserting" step recited in claim 21. Appellants make no additional arguments for claims 34–38 (Appeal Br. 14), and these claims fall with claim 33, from which they depend.

DECISION

The Examiner's decision to reject claims 1, 12–25, 27, 28, and 32–38 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED